IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CHEMISTRY COUNCIL, INC.,	:	
Plaintiff,	:	Civil Action No. _____
v.	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and NATIONAL INSTITUTES OF HEALTH,	:	
Defendants.	:	

COMPLAINT

Plaintiff American Chemistry Council, Inc. (the "Plaintiff"), by and through its undersigned attorneys, for its Complaint, alleges as follows:

INTRODUCTION

1. By this action, Plaintiff seeks relief directing the United States Department of Health and Human Services ("HHS") and the National Institutes of Health ("NIH") (each, a "Defendant"; collectively, the "Defendants") to produce information withheld in violation of the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552; the Shelby Amendment, Pub. L. No. 105-277, 112 Stat. 2681-495 (Oct. 21, 1998); and the Shelby Amendment's implementing regulations at 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d).

JURISDICTION AND VENUE

2. This action arises under the laws of the United States. Accordingly, the jurisdiction of this Court rests on 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. Venue is proper in this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1391(b), (e)(1).

THE PARTIES

4. Plaintiff is a nonprofit trade association organized under the laws of the State of New York and having its principal place of business at 700 Second Street, N.E., Washington, DC 20002. Plaintiff represents the leading companies engaged in the business of chemistry.

5. Defendants are agencies of the United States within the meaning of 5 U.S.C. § 552(f). Defendants also are awarding agencies within the meaning of OMB Circular A-110 (as codified at 2 C.F.R. § 215.36) and 45 C.F.R. § 74.36. Defendant NIH is a component entity of HHS.

FACTUAL HISTORY

I. The Report on Carcinogens

6. In 1978, Congress mandated that the Secretary of HHS (the "Secretary") "publish a biennial report which contains . . . [, *inter alia*,] a list of all substances . . . [that] are known to be carcinogens or may reasonably be anticipated to be carcinogens and . . . to which a significant number of persons residing in the United States are exposed [and] . . . information concerning the nature of such exposure . . . ." 42 U.S.C. § 241(b)(4)(A)-(B).

7. The Secretary delegated responsibility for the preparation of this report to the National Toxicology Program ("NTP"), a component entity of HHS, which regularly releases the Report on Carcinogens (the "RoC"). Twelve RoCs have been published since the report was first mandated.

8. The RoC is intended to be utilized by, *inter alia*, state, federal and local regulatory authorities as a "comprehensive" report of "all known or suspected carcinogenic

agents." H.R. Rep. No. 95-1192, at 28 (1978). Consistent with this objective, several agencies have promulgated regulations that impose obligations with respect to "carcinogens", where that term is defined, in part, by reference to the RoC. *See, e.g.*, 29 C.F.R. § 1910.1200(d)(4)(i), (g)(2) (the Occupational Safety and Health Administration obliges employers to obtain or develop material safety data sheets with respect to carcinogens that the employers manufacture, import or use); 40 C.F.R. § 707.60(c)(2)(i) (the Environmental Protection Agency ("EPA") requires exporters to provide notices of export for chemicals containing a certain percentage of carcinogens).

II. Formaldehyde and the Report on Carcinogens

9. Formaldehyde is a colorless, flammable gas that is used in aqueous solution to manufacture building materials and many household products. The majority of formaldehyde produced in the United States is used for the manufacture of resins, such as urea-formaldehyde, which are used to make adhesives for pressed wood products such as furniture, paneling and cabinets. Formaldehyde in aqueous solution also is used as a preservative in medical laboratories, mortuaries and consumer products. Further, formaldehyde gas is a byproduct of automobile combustion. Formaldehyde, which is essential for metabolic processes, is produced and exhaled as a gas in small amounts by most living organisms, including humans.

10. Formaldehyde was first listed in the second edition of the RoC, in 1981, as "reasonably anticipated to be a human carcinogen".

11. Until 2011, the RoC primarily limited formaldehyde's potential cancer associations in humans to certain nasopharyngeal cancers and cancers of the nasal cavity or paranasal sinuses.

III. The Zhang Study and Its Use By the Federal Government

12. In 2010, the Journal of Cancer, Epidemiology, Biomarkers & Prevention published a research article reporting on a study on formaldehyde, entitled *Occupational Exposure to Formaldehyde, Hematotoxicity, and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells*. That study is known as the "Zhang Study" because Dr. Luoping Zhang of the University of California at Berkeley School of Public Health was the lead author. Thirty-three other persons co-authored this research article, including eleven individuals who are affiliated with NCI.

13. According to the authors of this research article, the Zhang Study evaluated potential health effects of exposure to formaldehyde, including carcinogenicity, by examining a group of ninety-four workers in China. The authors concluded that formaldehyde exposure can have an adverse effect on the hematopoietic system, and that induction of leukemia (a type of cancer) by formaldehyde is "biologically plausible".

14. Upon information and belief, grants awarded after April 2000 from the Intramural Research Program of the NIH (the National Cancer Institute ("NCI")) and from the National Institute of Environmental Health Sciences ("NIEHS") funded the Zhang Study (grants R01ES017452 and P42ES004705, respectively) (the "Grants"; the recipient thereof being known as the "Grantee").

15. Upon information and belief, the terms of the Grants and applicable regulatory provisions require the Grantee to provide to the Defendants, upon the Defendants' request, research data relating to federally-funded published research findings that are used in developing agency actions having the force and effect of law.

16. In 2010, EPA used the Zhang Study in support of EPA's draft *Toxicological Review of Formaldehyde – Inhalation Assessment* for inclusion in EPA's Integrated Risk Information System.

17. In 2011, HHS published the 12th Edition of the Report on Carcinogens (the "12th RoC") in which NTP classified formaldehyde as "known to be a human carcinogen". NTP used and cited the Zhang Study to support a finding of an association between formaldehyde exposure and leukemia.

18. HHS's publication of the 12th RoC — classifying formaldehyde based upon an association with leukemia using the Zhang Study — has had the force and effect of law, including corresponding regulatory obligations. A federal law requires HHS to issue the RoC for use, *inter alia*, by federal regulatory authorities. For example, as a result of the inclusion of formaldehyde in the 12th RoC as a known human carcinogen, the Occupational Safety and Health Administration requires manufacturers of formaldehyde to obtain or develop material safety data sheets containing information with respect to formaldehyde's classification as a carcinogen.

IV. The Shelby Amendment

19. Congress in 1998 enacted legislation, commonly referred to as the "Shelby Amendment", to ensure public access to data that are developed through federally-funded research carried out by, *inter alia*, institutions of higher education.

20. Specifically, the Shelby Amendment establishes a right of the public to obtain such data by requiring the Director of the Office of Management and Budget ("OMB") to "amend[] Section __.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." Pub. L. No. 105-277, 112 Stat.

2681-495 (Oct. 21, 1998). The Shelby Amendment also authorizes the imposition of a reasonable user fee in certain circumstances, to cover the cost of obtaining the relevant data. *Id.*

21. OMB Circular A-110 is entitled "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations." The stated purpose of OMB Circular A-110 is to "set[] forth standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations." In accordance with the directive of the Shelby Amendment, the OMB Director in 1999 amended Section __.36 ("Intangible property") of OMB Circular A-110 to provide as follows:

> [I]n response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the Federal awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data.

Final Revision to OMB Circular A-110, 64 Fed. Reg. 54,926-01 (Oct. 8, 1999). OMB later codified this portion of OMB Circular A-110 at 2 C.F.R. § 215.36(d).

22. Other federal agencies have promulgated regulations to codify this portion of OMB Circular A-110. *See, e.g.*, HHS regulations at 45 C.F.R. § 74.36(d). These regulations require compliance by grant-awarding agencies with the procedures established under the FOIA.

V. Plaintiff's Request and Defendants' Response

23. By letter dated February 28, 2013, Plaintiff submitted a request to NIH for "copies of all Research Data related to" the Zhang Study (the "Requested Research Data"),

including those records associated with the grants that provided funding for the Study. (A copy of the February 28, 2013 request is attached hereto as Exhibit 1.) Plaintiff's request explained that the Requested Research Data consist of the "research data" accessible to the public via the Shelby Amendment and 45 C.F.R. § 74.36(d). *See* Ex. 1 at 3. Further, without limitation, Plaintiff's request enumerated certain specific categories of Requested Research Data encompassed by the request, such as: "[m]ethods for exposure sampling, data collection and analysis, including instrumentation and sampling locations"; and "Research Data identifying the specific factory at which each [Zhang] Study subject was employed." *See* Ex. 1 at 1-2.

24. NIH acknowledged receipt of Plaintiff's request by a letter dated March 5, 2013. (A copy of the March 5, 2013 letter is attached hereto as Exhibit 2.)

25. Despite the requirement to respond within ten working days of receiving a request pursuant to 45 C.F.R. § 5.35(b)(1), Defendants failed to respond within that time period.

26. On March 20, 2013, NIH wrote Plaintiff to advise that Plaintiff's request presented "unusual circumstances" requiring it to extend the time for responding to Plaintiff's request. (A copy of the March 20, 2013 letter is attached hereto as Exhibit 3.)

27. Despite the rule that such extensions may extend the time limit for no longer than ten working days pursuant to 45 C.F.R. § 5.35(c), Defendants have again failed to respond within that time limit.

28. Upon information and belief, Defendants have an obligation to obtain Requested Research Data.

29. Upon information and belief, the Grantee is in possession or control of Requested Research Data.

30. Upon information and belief, the Requested Research Data were used by the Federal Government in developing agency actions that have the force and effect of law.

CLAIM FOR RELIEF

COUNT I: VIOLATION OF THE FOIA, THE SHELBY AMENDMENT, OMB CIRCULAR A-110, AND HHS IMPLEMENTING REGULATIONS (5 U.S.C. § 552; 112 STAT. 2681-495; 2 C.F.R. § 215.36(d); 45 C.F.R. § 74.36(d))

31. The foregoing paragraphs are incorporated herein by reference.

32. On or about February 28, 2013, Plaintiff submitted to NIH a letter requesting the Requested Research Data, pursuant to and in compliance with the FOIA and applicable HHS regulations.

33. Upon information and belief, Defendants have a right and obligation to obtain all Requested Research Data.

34. Upon information and belief, the Grantee is in possession or control of Requested Research Data.

35. In response to a request submitted in conformance with the procedures established under the FOIA and applicable HHS regulations, Defendants are required by the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) to obtain and produce data related to federally-funded published research findings that are used in developing agency actions having the force and effect of law.

36. Plaintiff's February 28, 2013 request satisfies the requirements of the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) because Requested Research Data are research data relating to published research findings produced under a federal award, and because such research data and published research findings have been used by the Federal Government in developing agency actions that have the force and effect of law.

37. Defendants have violated the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d) and 45 C.F.R. § 74.36(d) by not obtaining Requested Research Data from the Grantee, and by not providing all Requested Research Data to Plaintiff.

38. Plaintiff has exhausted all available administrative remedies.

39. Plaintiff has been injured by being denied access to all Requested Research Data to which it is entitled and, as a result, being denied the ability to review all Requested Research Data.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff hereby requests:

a. An order declaring that Plaintiff is entitled to all Requested Research Data;

b. An order requiring Defendants to obtain Requested Research Data from the Grantee, and to provide all Requested Research Data to Plaintiff;

c. An order declaring Defendants' actions to be in violation of the FOIA, the Shelby Amendment, 2 C.F.R. § 215.36(d), and 45 C.F.R. § 74.36(d);

d. Reasonable attorneys' fees;

e. Costs of suit; and

f. Such other relief as this Court deems just and proper.

Dated: April 10, 2013

ARNOLD & PORTER LLP

By: _____

Blake A. Biles
(D.C. Bar No. 441679)
555 12th Street, N.W.
Washington, D.C. 20004
Telephone: (202) 942-5000
Facsimile: (202) 942-5999
E-mail: blake.biles@aporter.com

Kent A. Yalowitz
(*pro hac vice* application pending)
399 Park Avenue
New York, NY 10022
Telephone: (212) 715-1000
Facsimile: (212) 715-1399
E-mail: kent.yalowitz@aporter.com